

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Brian Eugene Baldwin et al.

Serial No.: 09/928,007

Filed: August 10, 2001

Confirmation No.: 6430

Atty. File No.: 50012-00004

For: METHOD, SYSTEM, AND APPARATUS  
FOR HANDLING, LABELING, FILLING  
AND CAPPING SYRINGES



Group Art Unit: 3721

Examiner: Brian D. Nash

#13  
K. Cobb  
8/28/03

<p align="center"><b>CERTIFICATE OF MAILING</b></p> <p>I HEREBY CERTIFY THAT this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: <u>Aug 8, 2003</u></p> <p align="center">MARSH FISCHMANN &amp; BREYFOGLE LLP</p> <p>By: <u>Michelle L. Wyss</u></p>
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**DECLARATION UNDER 37 CFR §1.132**  
**OF RANDALL W. SMITH**

**RECEIVED**  
**AUG 15 2003**

I, **Randall W. Smith**, state:

**TECHNOLOGY CENTER**

1. That I received a Bachelor of Science degree in Mechanical Engineering from Brigham Young University in 1983.

2. That I have 19 years of work experience in connection with the design and production of medical products, including the following positions:

a. Mechanical Engineer, Becton/Dickinson Advanced Diagnostic Systems, a provider of various medical products, including automated immunoassay instruments, 1983 to 1987;

b. Senior Engineer, Project and Research and Development Manager and Team Leader, Cobe Laboratories, Inc., a provider of various medical products, including dialysis products, 1987 to 1998; and,

c. Senior Engineer and Vice President of New Product Engineering, Baxa Corporation, a provider of syringes for oral liquid medications and intravenous drug administration, and automated systems for the preparation and administration of fluid medications, 1998 to Present.

3. That based on the foregoing, I believe I have at least ordinary skill in the field of medical products for fluid medication administration.

4. That I have reviewed and understand the specification and pending Claim 1 of the above-identified patent application, said Claim 1 being directed to an apparatus adapted for automated handling, comprising a plurality of syringe bodies and a flexible belt attached to the barrels of the syringe bodies, wherein the syringe bodies are disposable in a predetermined orientation with at least one end of each barrel being accessible, a copy of pending Claim 1 being attached hereto as **Appendix A** ("Pending Claim 1").

5. That, on information and belief, at the time of invention of Pending Claim 1, it was not known in the field of medical products for fluid medication administration to utilize an apparatus in which a plurality of syringe bodies were attached to a flexible belt, as specified in Pending Claim 1.

6. That I have reviewed U.S. Patent No. 3,823,818 to Shaw.

7. That, based on my review, Shaw is directed to thermoplastic container blow-molding (e.g. bottles) utilizing unfinished preforms, and is not directed to an apparatus adapted for automated handling of medical products for fluid medication administration, including in particular syringe bodies interconnected by a flexible belt.

8. That, in my opinion, as of the time of invention of Pending Claim 1, Shaw does not render obvious the invention of Pending Claim 1.

I HEREBY DECLARE THAT all statements made herein, of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

DATED this 30<sup>th</sup> day of July, 2003.



**Randall W. Smith**

**APPENDIX A**

Pending Claim 1 of U.S. Patent Application No. 09/928,007, filed August 10, 2001, entitled  
“METHOD, SYSTEM, AND APPARATUS FOR HANDLING, LABELING, FILLING AND  
CAPPING SYRINGES”

1. (Currently Amended) An apparatus adapted for automated handling,  
comprising:

a plurality of syringe bodies, each comprising a barrel; and,

a flexible belt fixedly attached to each said barrel of said plurality of syringe bodies,  
wherein said plurality of syringe bodies are positionable in a predetermined orientation and at  
least one end of each said barrel of said plurality of syringe bodies is accessible.